



# Medicines & Healthcare products Regulatory Agency

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[MHRA Website](https://www.mhra.gov.uk)

Our Ref: **FOI2025/00395**

19 May 2025

Dear [REDACTED]

Thank you for your Freedom of Information (FoI) request received on 23 April. You wrote:

*Please provide enough of the iatroX registration file (MHRA reference 2025042201417535) (<https://www.iatrox.com/>) to show the type and level of evidence the manufacturer relied upon to demonstrate the device's safety and performance at the time of self-declaration.*

*To protect any genuinely confidential material, I am asking only for summary-level information or suitably redacted extracts, namely —*

*Clinical evaluation / performance evidence*

*A synopsis (or redacted copy) of the Clinical Evaluation Report (CER) or Performance Evaluation Report that identifies:*

*the kinds of data reviewed (e.g. published literature, bench testing, post-market data, clinical studies) and their relative weighting;*

*any pivotal clinical investigations, including study design and subject numbers (titles and protocols may be redacted if necessary);*

*the manufacturer's overall conclusion on clinical safety and performance and any residual risks accepted.*

*Essential safety and performance requirements evidence map*

*The table or matrix that links each essential requirement of the UK MDR 2002 to the evidence cited (test reports, standards, literature, etc.). A redacted version showing document titles and evidence types, with confidential details removed, would be sufficient.*

*Post-market surveillance (PMS) approach*

*A brief description or summary table of the PMS activities the manufacturer committed to (e.g. complaints trend analysis, periodic safety update reports, user surveys).*

*Applied standards and intended purpose*

*The list of harmonised or designated standards applied;*

*the intended purpose statement and rule(s) used to justify Class I classification.*

*Registrant details*

*Name and address of the legal manufacturer and UK Responsible Person (if different).*

## MHRA Response

We confirm that we hold some of the information you have requested and provide it below. However, some of the information is exempt under Section 21(1) of the Freedom of Information Act because the information is reasonably accessible to you, as it is already in the public domain. To be helpful, we have provided the links below.

Following the review of the registration of iatroX AI Ltd and the Declaration of Conformity, this device does not meet the definition of a custom-made device ([Custom-made devices in Great Britain - GOV.UK](#)) as defined by UK MDR 2002.

For risk classification manufacturer should review the following guidance:

[MHRA Software flowchart](#)

[DocsRoom - European Commission](#) - Guidance document - Classification of Medical Devices - MEDDEV 2.4/1 rev.9

To determine the risk classification of the SaMD, manufacturer should review the following:

[IMDRF SaMD WG Software-Specific Risk N81 Final 0.pdf](#)

Please note that the MHRA does not itself assess or approve medical devices placed on the UK market, please see the guidance regarding the [UKCA mark and Conformity Assessment Bodies](#).

[Regulating medical devices in the UK](#); Overview. The Medicines and Healthcare products Regulatory Agency (MHRA) is responsible for regulating the UK medical devices market.

[Regulating medical devices in the UK - GOV.UK](#)

Further information about the conformity assessment process can be found in the following guidance; [Medical devices: conformity assessment and the UKCA mark - GOV.UK](#)

[Regulating medical devices in the UK](#); What you need to do to place a medical device on the Great Britain, Northern Ireland and European Union (EU) markets.

If you have any queries about this letter, please contact us quoting the reference number above.

Yours sincerely,

MHRA Central Freedom of Information Team  
Medicines & Healthcare products Regulatory Agency

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## Your right to complain under the Freedom of Information Act

If you are not happy with this response you may request an internal review by e-mailing [foi.request@mhra.gov.uk](mailto:foi.request@mhra.gov.uk) or by writing to: MHRA Central Freedom of Information Team, 10 South, Colonnade, Canary Wharf, London, E14 4PU

Any request for an internal review must be received by us within 40 working days of the date of this letter. Please note we are not obliged to provide a review if it is requested after more than 40 working days.

If you are not content with the outcome of the internal review, you may apply directly to the Information Commissioner's Office for a decision. Generally, the Commissioner cannot make a decision unless you have exhausted our own complaints procedure. The Information Commissioner can be contacted at: The Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire SK9 5AF.

Website: [ICO FOI and EIR complaints](#) or telephone 0303 123 1113.

## Re-use of our information

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this is otherwise stated. There are some restrictions on re-use under the OGL and these can be viewed here:

<https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/>